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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,866	06/04/2001	Mark K. Hechinger	1007-103.US	4668

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,866	HECHINGER, MARK K.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/26/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

DETAILED ACTION

Applicant's amendment filed on 1/26/2004 has been received and entered into record and considered.

Claims 1-19 and 26 are under examination. Claims 20-25 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

2. Claims 1-19, 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Preselected size of beads

Claim 1 recites a feature preparing beads of preselected sizes. However, applicant does not recite any range of sizes for the beads. It would inevitably impose undue burden to the ordinary skilled people in the art to optimize the size range of the beads to achieve the purported purpose.

Reducing Surfactancy of the beads

Claim 1 recites a feature “washing the beads in the buffer to form bead-buffer matrix and reducing the surfactancy of the beads to no more than 5% to allow antigen to attach to the beads.” It is unclear what agent(s) or some other extra step is needed to “reduce the surfactancy of the beads to no more than 5%”.

In the specification applicant states that “the surfactant amount, or the amount of chemical stabilizer used by the bead manufacturer to prevent clumping, within the stock solution should not exceed 5% in the initial (stock) solution.”

(See page 20, second paragraph) Does the method need a surfactant to reduce the surfactancy of beads? Assuming *arguendo*, it needs a surfactant, nevertheless it is unclear which surfactant applicant refers to. Is any surfactant suitable for this invention? Without any specific guidance to this critical step, i.e. reducing surfactant, it would impose undue burden to one skilled in the art to conduct the assay following the recited steps.

Prewashing Step

The examiner notices that the recited claim 1 does not include a prewashing step to remove surfactant. Applicant asserts that the prewashing steps “are very *important and significant* to the invention, since the prewashing removes surfactants and helps to prevent the clumping of the beads during the assay and flow cytometry.” (See page 25, third paragraph; page 31, second paragraph) Since this prewashing step is critical for the recited method,

Art Unit: 1641

without this limitation in the independent claim 1 would definitely impose undue burden to artisan in the art, and even may render the invention inoperative.

Scope of enablement

3. Claims 1-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carbonate buffer within a certain pH range, does not reasonably provide enablement for *any* buffer at *any* pH level. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Similarly, the instant invention is enable for certain percentage bovine serum albumin (BSA), not for *any* protein. (emphasis added)

Buffer and protein

The instant invention recites a method of preparing a bead-based assay by using a buffer with a protein. (See claim 1) However, the data in the specification merely disclose that a carbonate buffer has a pH of 9.0-10.0 is capable of accomplishing the purported purposes in facilitating the attachment of antigen of interest unto the beads. Similarly, applicant uses 0.1-5.0% bovine serum albumin as a blocking agents to eliminate the non-specific binding of the antigens. (See page 13, line 10 to page 14, line 10) Applicant assets the importance of the pH level in creating the bead-antigen assay. (page 31, second paragraph) Since, the binding of the antigen to the beads are delicate in terms of avoiding clumping, an ordinary skilled in the art would not choose *any* buffer at a

Art Unit: 1641

random pH level coupled with *any* percentage of blocking protein to achieve the intended purpose. The instant claimed language does not commensurate with the scope of the invention.

Coefficient of Variation (C.V.)

Applicant claims that the recited method includes preparing a preselected size beads having a coefficient variation less than 5%. (See claim 1) However, the data from the specification only supports that between ranges of 1.0% to 1.3%. (See page 18, second paragraph ; Table I) Applicant then use these beads to conduct attachment assay for various molecules, including RnP/sm, Sm, SS-A, SS-B and dsDNA.

Preselected size of beads

Applicant recites the instant method of preselecting size of beads for attachment of antigens. However, the specification only supports the ranges from 3 μ to 10 μ latex beads. (See page 11, last paragraph) No data support the notion that *any* size of the beads can accomplish the intended use for this invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1641

5. Claims 1-19, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, the preamble purported a “no wash” bead based assay.

However, in light of the specification, the current assay does need “washing” step, such as prewashing step recited in claim 17. Applicant needs to clarify which step or at what point, there is no need of washing.

With respect to claim 1, line 3, “a buffer” is vague and indefinite. It is not clear what “buffer” applicant refers to.

With respect to claim 1, line 4, “a protein” is vague and indefinite. It is not clear what protein applicant refers to.

With respect to claim 1, “preselected size” is vague and indefinite. It is unclear what size range applicant refers to.

With respect to claim 1, line 6, “the buffer” is vague and indefinite. It is not clear whether this buffer is the same as the first reagent and the “first reagent buffer” as in line 14.

Art Unit: 1641

With respect to claim 1, line 16, “second agent” needs to change to “the second agent” for consistency.

With respect to claim 1, line 7, “reducing the surfactancy of beads to no more than 5%” is vague and indefinite. It is unclear whether applicant means the surfactant used is no more than 5% or the surfactancy is no more than 5%. Furthermore, “5%” is vague and indefinite. It is unclear what applicant refers to 5%, e.g. v/v or v/w or something else. Similarly, claims 14-15 share the same problem as here.

With respect to claim 18 and 19, “the resuspension thereof” lacks antecedent basis.

Response to Applicant's Arguments

6. Applicant's arguments that neither Hansen et al. (US 5286452), Bignami et al. (US 5118607), nor Fulwyler et al. (Method in Cell Biology 1990, Vol 33, Chapter 15, page 613-629) individually or in combination, teach or suggest the recited method are persuasive. Accordingly, the rejections set forth in the previous Office Action is withdrawn. However, the instant new ground of enablement and scope of enablement rejections still render the recited invention unpatentable.

Conclusion

7. No claim is allowed.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



April 15, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/15/04